

PUBLIC HEALTH COUNCIL

Meeting of the Public Health Council, Tuesday, February 24, 2004 at 10:00 a.m., Massachusetts Department of Public Health, 250 Washington Street, Boston, Massachusetts. Public Health Council Members present were: Chair Christine Ferguson, Ms. Phyllis Cudmore, Mr. Manthala George, Jr., Ms. Maureen Pompeo, Mr. Albert Sherman, Ms. Janet Slemenda, Dr. Thomas Sterne, Mr. Gaylord B. Thayer, Jr., and Dr. Martin Williams. Attorney Donna Levin was present as General Counsel.

Chair Christine Ferguson announced that notices of the meeting had been filed with the Secretary of the Commonwealth and the Executive Office of Administration and Finance, in accordance with the Massachusetts General Laws, Chapter 30A, Section 11A 1/2. In addition Chair Ferguson announced the cancellation of the staff presentation: “Pediatric Asthma Surveillance in Massachusetts 2003” – Presentation by Suzanne Condon, Assistant Commissioner, Center for Environmental Health, Department of Public Health, due to a scheduling conflict.

The following members of the staff appeared before the Council to discuss and advise on matters pertaining to their particular interests: Dr. Paul Dreyer, Interim Associate Commissioner, Center for Health Quality Assurance and Control; Ms. Joyce James, Director, Determination of Need Program; Ms. Louise Goyette, Director, Office of Emergency Medical Services; and Attorney Carol Balulescu, Deputy General Counsel, Office of the General Counsel.

RECORDS OF THE PUBLIC HEALTH COUNCIL:

Records of the Public Health Council Meeting of October 28, 2003 were presented to the Council. After consideration, upon motion made and duly seconded, it was voted (unanimously) to approve Records of the Public Health Council Meeting of October 28, 2003.

PERSONNEL ACTIONS:

In a letter dated February 11, 2004, Ms. Katherine Domoto, M.D., Associate Executive Director for Medicine, Tewksbury Hospital, Tewksbury, recommended approval of the reappointment to the medical staff at Tewksbury Hospital. Supporting documentation of the appointee’s qualifications accompanied the recommendation. After consideration of the appointee’s qualifications, upon motion made and duly seconded, it was voted (unanimously): That, in accordance with the recommendation of the Associate Executive Director for Medicine of Tewksbury Hospital, under the authority of the Massachusetts General Laws, Chapter 17, Section 6, the following reappointment to the active medical staff at Tewksbury Hospital, Tewksbury, be approved for a period of two years February 1, 2004 to February 1, 2006:

REAPPOINTMENT : **STATUS/SPECIALTY:** **MEDICAL LICENSE:**

Elissa Ely, M.D. Active/Psychiatry 71620

In a letter dated February 9, 2004, Mr. Paul Romary, Executive Director, Lemuel Shattuck Hospital, Jamaica Plain, recommended approval of appointments and reappointments to the medical staff of Lemuel Shattuck Hospital. Supporting documentation of the appointees' qualifications accompanied the recommendation. After consideration of the appointees' qualifications, upon motion made and duly seconded, it was voted (unanimously): That, in accordance with the recommendation of the Executive Director of Lemuel Shattuck Hospital, under the authority of the Massachusetts General Laws, Chapter 17, Section 6, the appointments and reappointments to the medical staff of Lemuel Shattuck Hospital be approved as follows:

INITIAL APPOINTMENTS: **STATUS/SPECIALTY:** **MEDICAL LICENSE:**

Sabeen Chuadry, M.D. Consultant/Internal Medicine 219685
Peter Cohen, M.D. Active/Psychiatry 70532

REAPPOINTMENTS: **STATUS/SPECIALTY:** **MEDICAL LICENSE:**

Garo Damla, M.D. Consultant/Gynecology 77989
Leon Lai, M.D. Consultant/Internal Medicine 203137
Jeremy Ditelberg, M.D. Consultant/Pathology 159430
Tommy Sellers, M.D. Active/Psychiatry 38087

In a letter dated February 6, 2004, Mr. Blake Molleur, Executive Director, Western Massachusetts Hospital, Westfield, recommended approval of the appointments and reappointments to the active and consulting medical staff of Western Massachusetts Hospital. Supporting documentation of the appointees' qualifications accompanied the recommendation. After consideration of the appointees' qualifications, upon motion made and duly seconded, it was voted (unanimously): That, in accordance with the recommendation of the Executive Director of Western Massachusetts Hospital, under the authority of the Massachusetts General Laws, Chapter 17, Section 6, the following appointments and reappointments to the active and consulting medical staff of Western Massachusetts Hospital be approved:

APPOINTMENTS: **STATUS/SPECIALTY:** **MEDICAL LICENSE:**

Howard Raymond, M.D. Radiology 38313
Rinn Joseph, DMD Dentistry 20966

REAPPOINTMENTS:**STATUS/SPECIALTY:****MED. LICENSE:**

Theodore King, M.D.	Pulmonary/Geriatric Medicine	56940
Murray Watnick, M.D.	Radiology	29482
Robert White, M.D.	Urology	35343

* **Note** – Due to a scheduling conflict, the staff presentation, “**Pediatric Asthma Surveillance in Massachusetts 2003**” by Suzanne Condon, Assistant Commissioner, Center for Environmental Health, Department of Public Health, was not heard.

REGULATIONS:**REQUEST FOR FINAL PROMULGATION OF AMENDMENT TO 105 CMR 170.000: EMERGENCY MEDICAL SERVICES SYSTEM, FOR ACCREDITATION OF EMS TRAINING INSTITUTIONS:**

Ms. Louise Goyette, Director, Office of Emergency Medical Services, said, “The purpose of this memorandum is to request Public Health Council’s approval to promulgate final amendments to 105 CMR 170.000: Emergency Medical Services System, to implement Department accreditation of EMS training institutions. In addition, the amendments clarify and improve the standards to be met by non-accredited training program providers, and clarify and update the duties and responsibilities of Department-approved Chief Examiners, Examiners and Instructor/Coordinators. Some technical amendments to other portions of the EMS regulations are also included. These amendments were originally presented to the Council on December 16, 2003.”

Ms. Goyette continued, “Department approval of EMT training to date has largely been based on the review of documentation submitted by applicants on a course-by-course basis prior to each program. The administrative burden on the Department’s Office of Emergency Medical Services is enormous: some 200 initial, 500 refresher and 5,000 continuing education courses are reviewed and approved annually. Section 9 of M.G.L. c. 111C, amended as part of EMS 2000, gives the Department the authority to accredit institutions that provide courses in emergency medical care. The goal of accrediting EMS training institutions is to ensure and improve the quality of EMS training programs statewide. Major benefits are the reduction of the administrative burden of course-by-course approvals and the ability for OEMS to focus more on-site evaluation of training programs. Having accredited training institutions conduct the practical skills portion of the the state EMT certification exam will a) substantially reduce the time to certification and b) save some \$175,000 annually in exam administration costs to the Department. A Chief Examiner representing the Department will provide on-site supervision and accredited institutions will be required to provide Department-approved Examiners. In developing its plan for accreditation, the Department received the input of a broad community of interested parties, including the Emergency Medical Care Advisory Board. The Department met in June 2003 with representatives of

training institutions running Paramedic-level training programs. In addition, the Department met with the Chief Examiners, to discuss the planned transition of the practical skills exam administration to accredited institutions. Subsequently, the Department developed draft regulations and submitted them to the members of the full EMCAB in November 2003 for their review and comment.”

Ms. Goyette concluded, “The Department held a public hearing on Tuesday, January 20, 2004, in Boston. Comment was accepted until Friday, January 23, 2004 at 5 p.m. Oral and/or written comments on these regulations were received from eight organizations or individuals, as follows: State Rep. Brian Knuttila; the Director of the Institute for Emergency Medical Services at Northeastern University and the Director of the Paramedic Program at Massachusetts Bay Community College (jointly signed); the Chair of the EMS Management Department at Springfield College; the Director of the Paramedic Program at Springfield College; the President of Safety Program Consultants, Inc.; the Director of the Regional EMS Council for Region II; and the trauma coordinator for Saint Vincent Hospital.”

After consideration, upon motion made and duly seconded, it was voted unanimously to **approve the request for Final Promulgation of Amendment to 105 CMR 170.000: Emergency Medical Services System, for Accreditation of EMS Training Institutions:** that a copy of the approved regulations be forwarded to the secretary of the Commonwealth; and that a copy of the amended regulations be attached to and made a part of this record as **Exhibit Number 14,779.**

REQUEST FOR FINAL PROMULGATION OF AMENDMENTS TO 105 CMR 130.000: HOSPITAL LICENSURE AND 105 CMR 170.000: EMERGENCY MEDICAL SERVICES SYSTEM, FOR TRAUMA CARE SYSTEM IMPLEMENTATION:

Ms. Louise Goyette, Director, Office of Emergency Medical Services, said, “The purpose of this memorandum is to request the Public Health Council’s approval to promulgate final amendments to 105 CMR 130.000: Hospital Licensure, and 105 CMR 170.000: Emergency Medical Services System, to implement an additional element of “EMS 2000”: establishment of a statewide coordinated trauma care system. These amendments were originally presented to the Public Health Council on an informational basis on October 28, 2003. Section 11 of M.G.L. c 111C, enacted as part of EMS 2000, requires the Department to develop and implement a statewide trauma system. The statute set out parameters for such a system, and minimum elements to be addressed, such as requirements for hospital designation and standard of care, data collection, including establishment of a trauma registry, and pre-hospital care guidelines for triage and transport. In developing a trauma system, the Department was required by Section 13 (b) of the same chapter to establish a trauma system advisory committee, under the umbrella of the Emergency Medical Care Advisory Board (EMCAB), to be composed of an equitable balance of representatives from Regional EMS Councils, trauma centers and community hospitals. The Statewide Trauma Committee was established in early 2001, and met quarterly over the next two years. The Committee established four working

subcommittees—Hospital Designation, Clinical Care, Data Registry and Public Information which developed most of the substantive recommendations for a state trauma plan. Through this process, the Committee reached consensus and issued its recommendations for a state trauma care system, in April 2002. Those recommendations were reviewed by the full EMCAB in June 2002, and submitted to the Department for implementation. Based on the Committee's recommendations, the Department developed draft regulations and submitted them to the Statewide Trauma Committee in December 2002 for its review and comment. Revised draft regulations were submitted to members of the full EMCAB in September 2003. That comment was reviewed, and as appropriate, incorporated."

Ms. Goyette continued, "The Department held a public hearing on Monday, December 15, 2003, in Boston. Comment was accepted until Friday, December 19, 2003 at 5 p.m. Oral and/or written comments on these regulations were received from seven organizations or individuals, as follows: the Massachusetts Hospital Association (MHA); Caritas Carney Hospital; the Director of the Regional EMS Council for Region III; the trauma coordinator for Saint Vincent Hospital; the Fire Chief for the city of Gloucester; the Vice President and Chief of Emergency and Ambulatory Services at Sturdy Memorial Hospital, and the Chief Paramedic for Emerson Hospital EMS, who was also commenting on behalf of the Massachusetts Association of Hospital-Operated Paramedic Services (MAHOPS).

The Department asks that these amendments be approved for final promulgation. After consideration, upon motion made and duly seconded, it was voted unanimously to **approve (with changes) the Request for Final Promulgation of Amendments to 105 CMR 130.000: Hospital Licensure and 105 CMR 170: Emergency Medical Services System, for trauma care system implementation**; and that a copy of the amended regulations be forwarded to the Secretary of the Commonwealth; and that a copy of the amended regulations be attached to and made a part of this record as **Exhibit Number 14,780**.

REQUEST FOR FINAL PROMULGATION OF AMENDMENTS TO THE HOSPITAL LICENSURE REGULATIONS: 105 CMR 130.000 REGARDING THE DESIGNATION OF PRIMARY STROKE SERVICES:

Dr. Paul Dreyer, Interim Associate Commissioner, Center for Health Quality Assurance and Control, said, "Over the past several months, the Department has been working with clinicians, hospitals, and advocates to develop standards for designating Primary Stroke Services in hospitals that are equipped to rapidly triage and treat patients presenting with symptoms of acute stroke...Each year over 3500 Massachusetts citizens die from stroke. Stroke is the third leading cause of death in Massachusetts and a leading cause of disability. Stroke is a type of cardiovascular disease that affects the arteries leading to and within the brain. There are two major types of acute stroke. Acute hemorrhagic stroke occurs when a blood vessel, which carries oxygen and nutrients to the brain, ruptures and causes bleeding into or around the brain. Acute ischemic stroke occurs when a blood vessel to the brain is blocked by a clot. An estimated eighty percent of strokes are

ischemic. Historically, no effective treatment has been available for acute ischemic stroke. Clinical trials have established thrombolytic therapy as an effective treatment if administered within limited time parameters. Based on these clinical trials, the Food and Drug Administration approved the use of tissue-type plasminogen activator, a thrombolytic agent also known as t-PA, for patients with acute ischemic stroke if given within three hours of symptom onset. However, less than five percent of people with acute ischemic stroke receive thrombolytic agents within the recommended time frames. The American Heart Association and other clinical standard setting entities have recommended that Primary Stroke Services be established to ensure that clinically eligible patients are afforded the opportunity to receive this definitive care.”

Proposed Amendments to the Hospital Licensure Regulations

With the goal of improving the care and outcomes of acute ischemic stroke patients, the Department drafted proposed amendments to the hospital licensure regulations to establish standards for Primary Stroke Services. Under the proposed amendments, a hospital providing licensed emergency services may apply for designation. The standards, as originally proposed, included the following hospital requirements:

- 1) creation of an Acute Stroke Team, with a physician director who has training and expertise in cerebrovascular disease,
- 2) development and implementation of written care protocols,
- 3) availability of the service 24 hours per day, seven days a week,
- 4) development and implementation of effective communication with Emergency Medical Service personnel in the pre-hospital setting during the transportation of a patient with symptoms of acute stroke,
- 5) rapid availability of neuroimaging and other imaging, electrocardiogram, laboratory and neurosurgical services,
- 6) continuing health professional education,
- 7) development and implementation of quality assessment and improvement programs, and
- 8) data collection, with submission of select data elements to a data center approved by the Department.

Public Hearing and Comment

The Department conducted a public hearing on December 29, 2003. Approximately 30 people attended the hearing. Four people presented oral testimony. The Department also accepted written comments on the proposed amendments through January 9, 2004. The Department has made the following revisions based on the public comments:

- 1) 105 CMR 130.1412: Added a requirement that the hospitals provide to the community information on prevention of stroke, recognition of stroke symptoms, and stroke treatment.
- 2) Deleted the definition of Data Center and revised 105 CMR 130.1410, deleting the specifics regarding data elements. The Department will define the data collection and submission requirements in its advisory bulletin.
- 3) Replaced the words 'rapid' and 'rapidly' with 'prompt' or 'promptly' throughout the document, except in the definitions of Acute Hemorrhagic Stroke, Acute Ischemic Stroke and Acute Stroke and clarified in 105 CMR 130.1405 that time to treatment under the hospital's written care protocols must be consistent with time targets acceptable to the Department.

Recommendation:

The Department requests approval for final promulgation of the amendments as revised based on the public comments.

After consideration, upon motion made and duly seconded, it was voted unanimously to **approve the Request for Final Promulgation of Amendments to the Hospital Licensure Regulations: 105 CMR 130.000 Regarding the Designation of Primary Stroke Services**; that a copy of the approved regulations be forwarded to the Secretary of the Commonwealth; and that a copy be attached to and made a part of this record as **Exhibit Number 14,781**.

DETERMINATION OF NEED:

COMPLIANCE MEMORANDUM:

PREVIOUSLY APPROVED DON PROJECT NO. 4-3A06 OF MASSACHUSETTS GENERAL HOSPITAL - REQUEST FOR A SIGNIFICANT CHANGE TO MODIFY A CONDITION OF APPROVAL RELATING TO PROJECT FINANCING:

Ms. Joyce James, Director, Determination of Need Program, said, "The purpose of this memorandum is to present for Public Health Council action the request filed by Massachusetts General Hospital pursuant to 105 CMR 100.753 of the Determination of

Need Regulations, for a significant change to approved DON Project No. 4-3A06, acquisition of two combination Positron Emission Tomography/Computerized Axial Tomography scanners and associated renovation. The significant change seeks to modify a condition of project approval by changing the financing of the \$4,700, 000 (August 2001 dollars) maximum capital expenditure from 100% equity contribution to 20% equity contribution and a capital lease. Significant changes require the Council's action pursuant to 105 CMR 100.756 (G). Staff is recommending that the proposed significant change be approved."

Ms. James continued, "The holder states that the proposed amendment will allow the Hospital to assemble financing options that ensure more efficient and effective overall use of the Hospital's limited resources. Supporting documentation submitted at Staff's request indicates that the capital lease would allow the Hospital to take advantage of a current interest rate of 2.76% through Massachusetts Health and Educational Facilities Authority, compared to the 4.36% interest rate available to the Hospital at the time Project No. 4-3A06 was approved by the Department. The documentation also shows the opportunity costs of financing the MCE with 100% equity contribution and with 20% equity contribution plus a five year capital lease at 2.76%. Investing the \$4,700,000 conservatively at the five-year U.S. Treasury rate of 3.167%, the Hospital would realize \$474,062 in earnings. Investing \$3,760,000 (\$4,700,000 less 20% equity) over the same time period at the same conservative rate, the earnings would be \$379,250. Thus, though the proposed financing of 20% equity contribution and a capital lease, the Hospital would only forego \$379,250 in earnings instead of \$474,062. In reviewing the request for modification of the condition concerning project financing, Staff has examined whether the proposed financing of the MCE was reasonable in light of past decisions, were not foreseeable at the time the application was filed and were beyond the holder's control. Consistent with Council's past decisions, Staff finds that the proposed change in project financing was unforeseen at the time the application was filed, was beyond the control of the holder and will reduce the project's opportunity costs to the holder."

After consideration, upon motion made and duly seconded, it was voted (Chair Ferguson, Phyllis Cudmore, Matt George Jr., Maureen Pompeo, Albert Sherman, Janet Slemenda, Gaylord Thayer, Jr., Dr. Williams, in favor (Dr. Thomas Sterne recused himself from discussion and vote); **to approve, with conditions, Previously Approved DoN Project No. 4-3A06 of Massachusetts General Hospital's request for a significant change to modify a condition of approval relating to project financing.** This amendment is subject to the following conditions:

- 1) Massachusetts General Hospital shall contribute 20% equity contribution toward the final approved MCE of DoN Project No. 4-3A06.
- 2) All conditions attached to the original and amended DoN Project No. 4-3A06 shall remain in effect.

The meeting adjourned at 11:45 a.m.

Chair Christine Ferguson
Public Health Council

LMH/sb